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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/531,969	03/21/2000	Jan Geliebter	96700/596	6902

7590 04/19/2005

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EXAMINER	
KELLY, ROBERT M	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/531,969	GELIEBTER ET AL.	
	Examiner	Art Unit	
	Robert M. Kelly	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *50,54-56 and 59-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *50,54-56 and 59-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/2/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response of 2/2/05 has been entered.

Claims 51-53 and 57-58 are cancelled.

Claims 55-56 are amended.

Claims 60-64 are newly presented.

Claims 50, 54-56, and 59-64 are presently considered.

Information Disclosure Statement

Applicant has submitted a new copy of page 2 of the IDS of dated 7/8/04, deleting references titled "XP00...". However, there is no need to submit this IDS, as the references have all been considered for the portions submitted of each reference. The Examiner again has signed the references, but crossed them out for being duplicates, and indicated such. Applicant is not required to submit any more IDS pages with these references. Further the pagination has been renumbered with this submission, to reflect that only 1 page was submitted.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description

In light of Applicant's cancellation of claims 51-53 and 58, the rejections of those claims under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, are rendered moot, and thus, are withdrawn.

Claims 50, 54, and 59 remain rejected, and claims 60-61 and 64 are newly rejected as required by amendment, under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for reasons set forth in the previous official actions. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

It is noted that Applicant has amended the claims to longer specifically claim any calcium-sensitive, metabolically gated, or inward rectifier potassium channel proteins; however the broad claims still embrace these genera, as well as any potassium channel protein. Therefore, the rejections are maintained on all the bases discussed in the prior official action of 12/29/04, e.g., pp. 3-7)

Response to Arguments – Written Description

Applicant's arguments of 2/2/05 have been fully considered but are not found persuasive.

Applicant argues that the Application teaches gene therapy by using DNA encoding potassium channels proteins to induce relaxation of smooth muscles, two specific examples are provided: maxi-K and K-ATP, and there is a diverse repertoire of potassium channels having potentially important implications for the modulation of electrical activity in human smooth muscle cells, including coporal myocytes. Further, Applicant argues, over 30 potassium

channels were known at the time of invention by Applicant. (Applicant's response of 2/2/05, pp. 5-6, paragraph bridging.)

Such is not persuasive. First, Applicant is claiming potassium channel proteins, not potassium channels, while the Art recognizes many potassium channels, Applicant's careful wording evinces an intention to claim a broader genera than potassium channels. Second, even if the genera were amended to potassium channels, and with the knowledge of over 30 potassium channels at the time of invention, only two were known to be physiologically relevant to penile smooth muscles: K-ATP and maxi-K (SPECIFICATION pp. 27-28, paragraph bridging). Furthermore, it is clear from the aforementioned breadth above, Applicant is intending to claim potassium channels and potassium channel proteins which were not even known at the time of invention to be potassium channels. For example, the specification, at page 28, paragraph 3, discusses many SUR subunits and K-ATP-like channels, which are not even known to be potassium channels. Applicant's broad claim to potassium channel proteins certainly contemplates these proteins, as well as any potassium channel and the two potassium channels with any physiological relevance to penile smooth muscle. (These arguments have been previously presented in the prior official actions).

Applicant reviews the evidence provided by the Declaration of Dr. Christ of 5/20/03, and demonstrates that Kv1.5 and SK3 were both known in the art prior the priority date of 2/13/97 in the instant Application (Applicant's response of 2/2/05, p. 6, paragraph 2). In effect, Applicant is arguing, pursuant to the Applicant-requested interview placed in the record on 2/8/05, that more than two potassium channels known at the time of invention actually may be used in the claimed methods and are functional in relaxing penile smooth muscle.

Such is not considered persuasive. In addition to not overcoming the rejection on the basis of any potassium channel protein, reviewed above, such post-filing evidence was not in Applicant's possession at the time of filing, and the Artisan could not reasonably predict from Applicant's disclosure that Applicant was in possession of such evidence. Such is because Applicant has specifically stated that experimental data only demonstrates presence and physiological relevance of only two potassium channel subtypes for such penile smooth muscle: K-ATP and maxi-K (SPECIFICATION, p. 27, paragraph 2). From these two examples, the Artisan cannot determine the common structural requirement for any potassium channel protein that would be physiologically relevant in the penile smooth muscle. (e.g., Official Action of 12/29/04, pp. 2-7). Applicant's post-filing evidence, therefore, does not demonstrate possession at the time of filing.

Applicant reviews the declaration of Drs. Christ and Melman of 4/27/04, to argue again that the Examiner is misconstruing the statements of Applicant. Specifically, the paragraph describing the **physiological relevance** of only maxi-K and K-ATP is deemed to mean that such channels are the **endogenous** channels of **importance**, and that it was not meant to limit the invention, by which they actually mean any potassium channel protein (Applicant's argument of 2/2/05, pp. 6-7, paragraph bridging).

Such is not persuasive for reasons of record. Applicant did not state the only channels of any **endogenous importance** are maxi-K and K-ATP, but that, despite all the experimentation that has occurred, evidence exists for the **physiological relevance** of only two potassium channels in such smooth muscle: maxi-K and K-ATP. (Official Action of 12/29/04, pp. 6-7, and prior official actions.)

Applicant argues that the sentence bridging pages 27-28 of the specification is based upon an interpretation of previous studies of Dorschner and Benevides, to point out that the authors of these studies were discussing the such maxi-K and K-ATP are thought to be among the most important modulators of such smooth muscle. Therefore, Applicant argues, they did have possession of the genera, and through the interpretation provided by a reading of Dorschner and Benevides, the Artisan would have known that Applicant had possession of the presently claimed potassium channel proteins (Applicant's response of 2/2/05, pp. 7-8, paragraph bridging).

Such is not persuasive for reasons of record, as well as reasons brought forth in Applicant's argument. Applicant's argument specifically states that "[the two channel] subtypes are **thought to be among the most important**" (Id., emphasis added). It does not state that the two subtypes **are the most important of a larger genera**. Moreover, as Applicant quotes "there has been no rigorous characterization of the K+ channel subtype(s) that might be responsible for mediating these relaxing effects of the K channel modulators/openers in human corpora" (Id., quoting Lee, et al. (1999)). Hence, even the quoted reference recognizes that the characteristics of a potassium channel subtype that would work to relax penile smooth muscle are not possessed. Therefore, if Applicant's quote is based on these references, it is apparent that Applicant was not in possession of any potassium channel, much less the broader genera of any potassium channel protein. These arguments have been made in similar form in the previous Official Action of 12/29/05, pp. 3-7).

Therefore, it is maintained that Applicant was not in possession of the genera of any potassium channel protein that enhances relaxation of the penile smooth muscle for reasons of record.

Enablement

In light of Applicant's cancellation of claims 51-53 and 57-58, the rejections of those claims under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed methods to the extent of DNA sequences encoding potassium channel proteins that are K-ATP or maxi-K, does not reasonably provide enablement for all other methods embraced by the claims, are rendered moot, and thus, are withdrawn.

Claim 50, 54-56, and 59 remain rejected, and claims 60-64 are newly rejected for reasons necessitated by the amendments, under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed methods to the extent of DNA sequences encoding potassium channel proteins that are K-ATP or maxi-K, does not reasonably provide enablement for all other methods embraced by the claims for reasons of record. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Moreover, Claims 60-64 are newly rejected for reasons of record, under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating a subject suffering from heightened contractility of the penile smooth muscle comprising the direct introduction of a DNA encoding a promoter operably linked to a sequence encoding maxi-K or K-ATP into the penile smooth muscle, thereby causing the encoded potassium channel to be

expressed, thereby treating the heightened contractility of the penile smooth muscle, does not reasonably provide enablement for treating any disorder or disease in a subject. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Applicant is directed to the rejection of 6/6/01 for the argument presented to demonstrate a lack of reasonable predictability in treating any disease or disorder with such nucleic acids (Official Action of 6/6/01, pp. 5-11).

Response to Arguments – Enablement

Applicant's arguments of 2/2/05 have been fully considered but are not found persuasive.

Applicant argues that the specification provides two working examples of DNAs encoding either maxi-K or K-ATP, evidence of two additional potassium channels which are effective at inducing relaxation of corporeal smooth muscle, and the presence in the art of at least thirty K+ channels. Therefore, Applicant argues, by the teachings of the working examples and the specification, the Artisan could reasonably predict the working embodiments embraced by Applicant's claims (Applicant's response of 2/2/05, pp. 8-9, paragraph bridging).

Such argument is not found persuasive for reasons of record. Applicant specifically stated in the specification that "Despite the plethora of known [potassium-channel] subtypes, experimental and clinical data in human corporal smooth muscle provide evidence for the presence and physiological relevance of only two: (1) the metabolically-gated [potassium] channel (i.e., [K-ATP]), and (2) the large-conductance, calcium sensitive [potassium] channel (i.e., the [K-Ca] or maxi-K channel) ...." (SPECIFICATION, p. 27, paragraph 2). As such, the Artisan could not reasonably predict that any other potassium channel would be efficacious in

the presently claimed methods (e.g., Official Action of 30 January 2004, p. 5, paragraph 1; previous Official Action of 12/29/04, pp. 7-8). As such, provided the number of potassium channels known in the art, and the larger number of potassium channel proteins, it would have required undue experimentation to find the other working embodiments embraced by Applicant's claims. Such is addressed throughout the prior office actions.

Moreover, Applicant has not presented any reasons why any treatment may be effected in a subject by the introduction of such DNA sequences into the penile smooth muscle.

Therefore, claims 50, 54, 59, and claims 60-64 are rejected for reasons of record.

Conclusion

No claim is allowed for reasons of record.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Kelly whose telephone number is (571) 272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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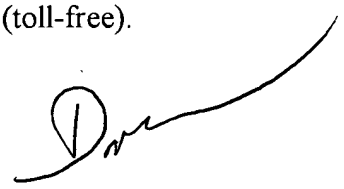

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